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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,685

07/11/2006

Egon Luther

ZEI-3286/500343.20307

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26418

7590

09/01/2009

REED SMITH, LLP

ATTN: PATENT RECORDS DEPARTMENT

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NEW YORK, NY 10022-7650

EXAMINER

LIPITZ, JEFFREY BRIAN

ART UNIT

PAPER NUMBER

3769

MAIL DATE

DELIVERY MODE

09/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,685	Applicant(s) LUTHER ET AL.	
	Examiner JEFFREY B. LIPITZ	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-19 and 21-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-19 and 21-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings were received on May 4th, 2009. These drawings are accepted.

Response to Arguments

Applicant's arguments, filed May 4th 2009, with respect to the 112 First Paragraph rejections have been fully considered and are persuasive. The 112 First Paragraph rejection of claim 22 has been withdrawn.

Applicant's arguments with respect to the prior art rejections of claims 13-19 and 21-26 have been considered but are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The wavelength of 365 nm is in the UV spectrum, not the visible spectrum. How is this light used to observe the patient's eye without ?

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the parallel beam path of the observation system". There is insufficient antecedent basis for this limitation in the claim.

Claims 16 and 18 recite a narrow-band short-wavelength range and a narrow-band long wavelength range, respectively. Neither of these ranges are known in the art or defined in the written disclosure. What are they?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-15, 21 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Sumiya (US 6,585,723 B1).

Regarding claims 13, 25, and 26, Sumiya teaches an illumination and irradiation unit, which is comprised of an observation system or optical system (30) and a corneal shape measurement optical system (10). The corneal shape measurement optical system (10) contains an illumination source (11) and a means for coupling light or a dichroic mirror (21) from the illumination source (11) into the parallel beam path of the observation system (30; Column 3, Lines 35-67; Column 4, Lines 1-17; Figure 2).

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Sumiya also teaches a control unit (40) that controls illumination source (11), and the means for generating specific illumination patterns or profiles (ie...lens 18 and scanning mirrors 19 and 20). In addition, Sumiya teaches a lens 12, a pinhole 13, a beam splitter (14), a quarter waveplate (16), and a dichroic mirror (17), a lens (18), and scanning mirrors (19 and 20) that generate specific illumination profiles and patterns (Column 6, Lines 47-67). Specifically, the pinhole (13) can be construed as a diaphragm, and the lenses can be construed as optical filters. All of the aforementioned components are capable of enabling generation of specific illumination patterns and or profiles. Many of the components are optoelectronic light modulators, since they are controlled by electronic means or driving circuit (46; Column 5, Lines 35-67).

The corneal shape measurement optical system (10) is arranged in a shared housing (1) with other optical systems and a control system. The corneal shape measurement optical system (10), the observation optical system (30), the laser irradiating optical system (25), the eyeball position detecting optical system (35), and the control system (40) are all used in combination with one another to perform corneal surgery (Column 3, Lines 2-25; Figures 1 and 2).

Regarding claims 14-15, Sumiya teaches a computer or monitoring unit (8) comprised of an input unit (41), a processing unit (42), a display unit (43), and an output unit (44). The processing unit (42) processes signals sent from the photodetector (23), signals sent from the corneal shape measurement optical system (10) and the inputted irradiation conditions in order to obtain ablation data. The data processed by the processing unit (42) is sent to the control system (40). Processed data may also be sent

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to the display unit (43). In addition to controlling the processing unit (42) and the control system (40), the computer (8) functions at least at the level of a basic computer, which can store or record ablation data or radiation dosage, irradiation patterns and positions. Sumiya specifically mentions that it has more than one interface for transferring data (a printer and a floppy disc drive; Column 3, Lines 21-24; Column 5, Lines 35-60); however, since computer (8) presumably can function as a basic computer, it would also contain other interfaces for transferring data such as USB ports, data DVD writer, data CD writer, a zip drive, etc....

Regarding claim 21, Sumiya teaches a dichroic mirror or beamsplitter (21) that enables the optical axis of the measurement optical system (10) and laser irradiating optical system (25) to be coaxial with the optical axis of the observation optical system (30). In addition, the dichroic mirror (21) only permits the transmission of visible light, reflecting the infrared laser beam and the exciter laser beam (Columns 3, Lines 62-67; Column 4, Lines 1-9). Thus, the dichroic mirror (21) protects the observer from unwanted radiation by filtering out the exciter and infrared laser beams.

Regarding claim 23, Sumiya teaches that there is an eyeball position detecting optical system or eyetracker unit (35) and a corneal shape measurement unit (10; Columns 4-5, Lines 61-34).

Regarding claim 24, Sumiya teaches that the observation optical system (30), which includes binocular microscope (3) and illumination unit (4), is illustrated as modular units for installation in the parallel beam path of the laser irradiating optical system (25; Figure 1). In other words, the observation optical system (30), containing

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the illumination unit (4) and the microscope unit (3), is attached to the main body (1) containing other subassemblies by the arm portion 2 (Column 3, Lines 3-25). Since several components of the observation optical system (3) and the corneal shape measurement optical system 10 (construed as the illuminating and irradiating unit as claimed) are shared, therefore both modular units are designed for retrofit installation, since each unit requires the other in order to properly function.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18, 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sumiya (as discussed supra).

Regarding claims 18 and 19, Sumiya teaches that the illumination source emits light at about 800 nm (Column 4, Lines 1-4). However, he does NOT teach that the laser beam (11) generates illumination light around 690 nm, as claimed. However, Sumiya does teach the use of additional illumination sources (4) for providing visible light, which is approximately 380-750 nm (Column 4, Lines 37-44). Furthermore, Applicant provides no rationale for using one illumination wavelength over another. Therefore, Examiner interprets any light source as an illumination source if that light is capable of being used for illumination.

Regarding claim 22, Sumiya teaches does NOT teach that the illumination source (11) is not arranged within the illumination unit. However, making an element separate is not of innovation. It would have been an obvious matter of design choice to make the illumination source separate from the illumination unit or to make the illumination unit a modular unit for retrofit installation into an ophthalmic instrument, since such modifications would have involved making the parts separately or portable. Making a part separate, if it is desirable, is generally recognized as being within the level of ordinary skill in the art. In re Dulberg, 289 F.2d 522, 129 USPQ 348, 349 (CCPA 1961). Furthermore, Applicant admits that positioning light sources outside of a main housing, and using a light guide or conductor to transmit the light to a main housing is common to one of ordinary skill in the art (Applicant's Arguments/Remarks: Pages 10-11).

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sumiya as applied to claim 13 above, and further in view of Haisch (20040152987).

Regarding claims 16-17, Sumiya does not teach that the illumination source has emits a narrow band light around 365 nm, as claimed. Attention is directed to Haisch, who teaches an inspection system for observing a fluorescent marker in a tissue (Abstract). Haisch teaches using an ultraviolet illumination source to excite a fluorescent marker (Paragraph [0014]). It would have been obvious to use a UV source for illumination of tissue in instances where there is auto-fluorescence of the tissue in the UV spectrum or in instances where a fluorescent dye is added to the tissue to

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provide fluorescence in response to UV light. The choice of UV illumination wavelengths will depend on the excitation wavelength of the tissue or dye. Hoechst dye, for example, is excited at about 365 nm, and will result in fluorescence of cell nuclei.

Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sumiya as applied to claim 13 above, and further in view of Wrobel et al. (20050107708), hereinafter Wrobel.

Regarding claim 27-29, Sumiya does NOT teach that the optoelectronic light modulator is a DMD or LCOS. Attention is directed to Wrobel who teaches an arrangement and method for illuminating the lens of the eye (Title). Wrobel teaches a DMD, a transmissive LCD, a self-luminous LED, or an organic LED for use as an optoelectronic component for generation of structured illumination (Paragraphs [0019] and [0022]). It would have been obvious to include any of these elements with the invention of Sumiya, because these elements enable a laser beam to have very high resolution, when forming specific profiles and patterns of irradiation (Paragraph [0009]).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY B. LIPITZ whose telephone number is (571)270-5612. The examiner can normally be reached on Monday to Thursday, 10 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry M. Johnson III can be reached on (571)272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JEFFREY B LIPITZ/
Examiner, Art Unit 3769

/Ahmed M Farah/
Primary Examiner, Art Unit 3769